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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,086	07/23/2001	En Li	0609.4560002	6968
26111	7590	01/26/2006	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/720,086

**Applicant(s)**

LI ET AL.

**Examiner**

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,13 and 25-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,13 and 25-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendments and Arguments***

1. Claims 1, 3-10, 13 and 25-50 are pending.  
Claims 8-10 have been amended.  
Claims 1, 3-10, 13 and 25-50 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Priority***

3. There continues to be insufficient proof that the proper sequences in the instant application and corresponding clones are one in the same as those listed in the priority documents. Applicants have submitted two declarations under 37 C.F.R. 1.132 signed by Kenneth D. Bloch, M.D and an inventor, En Li, Ph.D. The declaration signed by Dr. Bloch attests the deposited clone, ATCC Deposit No. 98809 is the same as the deposited clone in the instant application and SEQ ID NO: 3 corresponds to said deposit. However, the declaration signed by Dr. Li presents some ambiguity, see page 2 of declaration, paragraph 8. It is noted therein the deposited clones are *currently believed* to be the same as the coding sequence of currently amended SEQ ID NO: 1 and SEQ ID NO: 2. Essentially, it is not clear if SEQ ID NO: 1 is the same as ATCC Deposit No. 2099933 and if SEQ ID NO: 2 is the same as ATCC Deposit No. 209934. Applicants are requested to make statements with unswerving clarity. Consequently,

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the declaration signed by Dr. Li is not acceptable. Given a claim can only receive one priority date claims 1, 3-9, 13 and 25-50 continue to have a priority date of July 31, 2001. Only claim 10 is afforded the priority date of June 25, 1998.

### ***Withdrawn Objections***

#### ***Specification***

4. The drawings, Figures 1C, 2C, 2B, 2C, and 3B within the specification are no longer objected to under 35 U.S.C. 132 because it does not introduce new matter into the disclosure.

### ***Withdrawn Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112***

5. The second enablement rejection of claims 1, 3-10, 13 and 25-50 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claimed invention is withdrawn.

6. The rejection of claim 8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicants' pointedly expression where adequate support can be found for the claim limitations, see Remarks, page 23.

***Claim Rejections - 35 USC § 102***

7. The rejection of claim 10 under 35 U.S.C. 102(b) as being anticipated by Okano et al. (Nature Genetics 19:219 and 220, July 19, 1998), as evidenced by Accession numbers AF068625, AF068626 and AF068627 (December 6, 1999) is withdrawn in light of the information provided in the Bloch declaration submitted November 7, 2005.

8. The rejection of claim 10 under 35 U.S.C. 102(b) as being anticipated by Xie et al. (Gene 236(1): 87-95, 1999), as evidenced by Accession number AF067972 (February 12, 2001) is withdrawn in light of the information provided in the Bloch declaration submitted November 7, 2005.

***Claim Rejections - 35 USC § 103***

9. The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over by Okano et al. (Nature Genetics 19:219 and 220, July 19, 1998), as evidenced by Accession numbers AF068625, AF068626 and AF068627 (December 6, 1999), and in view of U.S. Patent 6,492,168 BI (April 22, 1998) is withdrawn in light of the information provided in the Bloch declaration submitted November 7, 2005.

10. The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Xie et al. (Gene 236(1): 87-95, 1999), as evidenced by Accession number AF067972 (February 12, 2001), and in view of U.S. Patent 6,492,168 BI (April 22, 1998) is

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withdrawn in light of the information provided in the Bloch declaration submitted November 7, 2005.

***Double Patenting***

11. The provisional rejection of claims 1, 3-10, 13 and 25-50 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10, 13, 24-37 and 51-55 of copending Application No. 10/623,813 (filed July 22, 2003) because claims 1-10, 13, 24-37 of 10/623,813 have been cancelled.

***Maintained Objections***

***Specification***

12. The drawings originally filed with the specification continue to be objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure.

Polynucleotides shown in Figures 1A-1 to 1A-4, 1B-1 to 1B4, 2A, 2B, 3A-1 and 3A-2 do not have adequate 35 U.S.C. 112, first paragraph support in the priority documents by reference to the deposits. For the reasons set forth in the Priority section the objection is maintained.

***Maintained and New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

13. The rejection of claims 1, 3-10, 13 and 25-50 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claimed invention is maintained and made.

Applicants have pointed out to the Examiner inconsistencies in the application of the instant rejection as well as the now withdrawn second enablement rejection. The Examiner appreciates Applicants' raising the issue. Applicants cite the Examiner's previous rejections predicated upon the previously examined subject matter. Applicants assert they have amended claims to recite a specific function and consequently the pending rejection should be withdrawn. Applicants further assert the claims limit the functions polynucleotides to that of probes or primers and all claims are enabled by the specification, see page 20 of the Remarks. Applicants' arguments and points of view have been carefully considered but found unpersuasive.

The making of the claimed polynucleotides may not be burdensome given one of ordinary skill in the art is given adequate information such as which residues should be mutate, deleted, substituted or unchanged. The amount of experimentation required to undertake such tasks would be length and problematic. There would be arbitrary selection required by one of ordinary skill in the art. Afterwards, one would need to test which variant molecule would function as required by the claims. Applicants' specification does not provide adequate guidance and does not provide adequate information enabling the making and using of variant molecules and a single polynucleotide sequence as listed in claims 1(f), 8(b), 9(b) and 10(b). The specification does not provide guidance for implementing the method of claim 13 with a mutant polypeptide encoded by a nucleic acid of claim 1 in particular those of sections e and f of claim 1. Given the insufficient guidance, the changes which must be made in the nucleic acid sequences of SEQ ID NO: 1-4, which results in nucleic acid sequences with

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90% identity and the implementation of one polynucleotide sequence is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue.

14. The rejection of claim 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicants argue *In re Ruschig* is not valid to the instant case and note the formula on page 21 of the specification, lines 17-25 discloses a genus of nucleotide fragments encompassing a range of sizes. Applicants further argue "...a person of ordinary skill would envision each fragment size in view of the formula because the fragment size is the only variable.", see Remarks, page 22, first full paragraph. These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants' specification is still remiss of sufficient information, guidance and sincere contemplation of an oligonucleotide probe or primer at least 100 contiguous nucleotides in length. Applicants' position is that a skilled artisan would readily arrive at the contemplation of at least 100 contiguous nucleotides of SEQ ID NO: 3. The Examiner does not concur and does not note significant information that leads the skill artisan to such contemplation.

#### ***Claim Rejections - 35 USC § 102***

15. The rejection of claims 1, 3-9 and 25-50 under 35 U.S.C. 102(b) as being anticipated by Okano et al. (Nature Genetics 19:219 and 220, July 19, 1998), as



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evidenced by Accession numbers AF068625, AF068626 and AF068627 (December 6, 1999) is maintained.

Applicants have supplied declarations in order to obviate the instant rejection. As noted in the Priority section of this Action the Li Declaration submitted November 7, 2005 is not accepted. Consequently, for the reasons of record the rejection is maintained.

16. The rejection of claims 1, 3-9 and 25-50 under 35 U.S.C. 102(b) as being anticipated by Xie et al. (Gene 236(1): 87-95, 1999), as evidenced by Accession number AF067972 (February 12, 2001) is maintained.

Applicants have supplied declarations in order to obviate the instant rejection. As noted in the Priority section of this Action the Li Declaration submitted November 7, 2005 is not accepted. Consequently, for the reasons of record the rejection is maintained.

***Claim Rejections - 35 USC § 103***

17. The rejection of claims 1, 3-9, 13 and 25-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Okano et al. (Nature Genetics 19:219 and 220, July 19, 1998), as evidenced by Accession numbers AF068625, AF068626 and AF068627 (December 6, 1999), and in view of U.S. Patent 6,492,168 B1 (April 22, 1998) is maintained.

Applicants have supplied declarations in order to obviate the instant rejection. As noted in the Priority section of this Action the Li Declaration submitted November 7,

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2005 is not accepted. Consequently, for the reasons of record the rejection is maintained.

18. The rejection of claims 1, 3-9, 13 and 25-50 under 35 U.S.C. 103(a) as being unpatentable over Xie et al. (Gene 236(1): 87-95, 1999), as evidenced by Accession number AF067972 (February 12, 2001), and in view of U.S. Patent 6,492,168 BI (April 22, 1998) is maintained.

Applicants have supplied declarations in order to obviate the instant rejection. As noted in the Priority section of this Action the Li Declaration submitted November 7, 2005 is not accepted. Consequently, for the reasons of record the rejection is maintained.

### ***Double Patenting***

19. The provision rejection of claims 1, 3-10, 13 and 25-50 under 35 U.S.C. 101 as claiming the same invention as that of claims 51-55 of copending Application No. 10/623,813 (filed July 22, 2003) is maintained.


20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**

  
Alana M. Harris, Ph.D.  
22 January 2005